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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,603	03/08/2007	Rene Djurup	DJURUP2	2533

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,603	DJURUP ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,19,21-29 and 44-57* is/are pending in the application.

4a) Of the above claim(s) *2,5,8,9,14-16,21,23,25,28 and 44-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7,10-13,18,19,22,24,26,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/08/2007; 09/20/2007* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 03/08/2007, has been entered.

Claims 17, 20 and 30-43 have been canceled.

Claims 44-57 have been added.

Claims 1-16, 18-19, 21-29 and 44-57 are pending.

Election/Restrictions

2. Upon further consideration, the restriction requirement between groups I and II (i.e., composition of antibody and the cell producing the antibody) has been withdrawn. Claims 25 and 26 have been rejoined with group I.

Applicant's election with traverse of group I, drawn to drawn to an antibody against human heparin binding protein (hHBP) and a pharmaceutical composition comprising the antibody; and F19A5B4antibody as the specific anti-inflammatory antibody that binds residues 20-44 of SEQ ID NO: 1 in the reply filed on 09/15/2008 is acknowledged.

The traversal is on the ground(s) that the Flodgaard reference (WO 00/66151, reference of record, cited on IDS) used in Restriction Requirement, mailed 05/14/2008, teaches the anti-hHBP antibody in present tense, thus suggesting no such antibody was in fact made. This is not found persuasive because the Flodgaard reference is indeed prior art over the present application. Therefore, the antibody taught by the reference, regardless in present or past tense, constitutes prior art. Given that the reference teaches a polyclonal antibody to hHBP (on page 16), it would bind to the epitope recited in the present claims because polyclonal antibodies are known to bind to multiple epitopes. Therefore, the technical feature of the present application does not contribute over prior art, thus the special technical feature does not exist.

The requirement is still deemed proper and is therefore made FINAL.

In response to Applicant's request for consideration of rejoinder, the following is noted:

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 2, 5, 8, 9, 14-16, 21, 23, 25, 28 and 44-57 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1, 3, 4, 6, 7, 10-13, 18, 19, 22, 24, 26, 27 and 29 are currently under examination as it reads on a composition comprising an anti-hHBP antibody that is anti-inflammatory.

Priority

3. The domestic priority date for claims 1, 3, 4, 6, 7, 10-13, 18, 19, 22, 24, 27 and 29 is deemed the effective filing date of international application, PCT/DK04/00634, i.e., 09/17/2004.

Applicant's claim for foreign priority is acknowledged. Priority application, PA 2003 01369 appears to provide sufficient written description for the claims under examination.

Information Disclosure Statement

4. The information disclosure statement filed 03/08/2007 and 09/20/2007 have been considered by Examiner.

Specification

5. Applicant is invited to review the application for spelling errors, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Objections

6. Claim 19 is objected to under 37 CFR 1.75(c) as being an improper multiply dependent claim because of the language "as defined in claims 10-13". The claim must be referred to in the alternative. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 4, 6, 7, 10-13, 18, 19, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for all "**homologues of hHBP**" as targets of the claimed antibody because there is a lack of sufficient written description to support the claimed genus of hHBP homologues which includes homologues from multiple species.

The standard for Written Description is met by "showing that an invention is complete by disclosure of sufficiently detailed, **relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure**, or some combination of such characteristics." See Enzo Biochem., Inc. v. Gen-Probe Incorporated 323 F.3d 956 (Fed. Cir. 2002).

In addition to hHBP set forth in SEQ ID NO: 1, Applicant discloses two species of homologues of hHBP, i.e., a porcine heparin binding protein (pHBP) (SEQ ID NO: 588) and human neutrophil elastase (hNEL) (SEQ ID NO: 589) (see, e.g., page 8, lines 23). There is no description of structural features shared by these disclosed species. Without such critical identifying features, one skilled in the art would not be able to recognize other species/members of the genus of homologues of hHBP.

Furthermore, the instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. A person of skill is well aware, at the time of the invention was made, that

different molecules, even with sequence similarity, do not necessarily have the same function.

For example, Attwood (Science 290: 471-473, 2000) teaches that “[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

Similarly, Skolnick et al. (Trends in Biotech. 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

Therefore, the disclosed species of homologues of hHBP, i.e., pHBP and hNEL, are not sufficiently representative of the genus of homologues of hHBP because the disclosure fails to describe the common attributes or characteristics that identify members of the genus of homologues of hHBP, known and unknown at the time the invention was made.

As the hHBP homologues are targets of the claimed antibodies, Applicant has not provided a sufficient written description of all the antibodies that are capable of binding to all the homologues of hHBP for the following reasons.

Other than the antibodies binding to the disclosed species of “hHBP homologous”, i.e., hHBP, pHBP and hNEL, there does not appear to be an actual reduction to practice of an antibody that binds other species of homologous of HBP, nor is there a complete or partial structure of an antibody capable of binding a HBP that is other than hHBP, pHBP or hNEL in detailed drawing or through a structural chemical formula, e.g., sequence of the antibody.

Furthermore, a skilled artisan is well aware that such antibodies binding to hHBP, pHBP or hNEL would not reasonably be expected to be reactive with all members of the genus of homologues of hHBP. For example, Lederman et al. (Molecular Immunology

28: 1171-1181, 1991; see entire document) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody. Further, Li et al. (PNAS 77: 3211-3214, 1980; see entire document) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Therefore, the specification does not provide for sufficient written description to reasonably convey to one skilled in the relevant art that, at the time the application was filed, Applicant had possession of all antibodies capable of binding to all homologues of hHBP.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co*. 43 USPQ2d 1398.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

9. Claims 1, 3, 4, 6, 7, 10-13, 18, 19, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pHBP and hNEL as homologues of hHBP, does not reasonably provide enablement for all homologues of hHBP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Regarding the instant claim limitations, the specification does not appear to provide an adequate enabling description for all "**homologues of hHBP**" as targets of the claimed antibody because there is a lack of sufficient guidance to enable on skilled

in the art to make all the hHBP homologues which includes homologous from multiple species.

In addition to hHBP set forth in SEQ ID NO: 1, Applicant discloses two species of homologues of hHBP, i.e., a porcine heparin binding protein (pHBP) (SEQ ID NO: 588) and human neutrophil elastase (hNEL) (SEQ ID NO: 589) (see, e.g., page 8, lines 23). There is no description of structural features shared by the disclosed species, hHBP, pHBP and hNEL. Without such critical identifying features, one skilled in the art would not be able to make other species/members of the genus of homologues of hHBP.

Furthermore, the instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure to enable a person of skill to make or use other species of the genus homologues of hHBP. A person of skill is well aware, at the time of the invention was made, that different molecules, even with sequence similarity, do not necessarily have the same function.

For example, Attwood (Science 290: 471-473, 2000) teaches that “[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

Similarly, Skolnick et al. (Trends in Biotech. 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

Regarding the breadth of the claim, one skilled in the art cannot make all the homologues of hHBP based on the disclosed species, i.e., pHBP and hNEL, without undue experimentation because disclosure fails to describe the common attributes or characteristics that identify members of the genus of homologues of hHBP, known and unknown at the time the invention was made. Therefore, the disclosed species of

homologues of hHBP, i.e., pHBP and hNEL, do not sufficiently enable the breadth of the entire genus of homologues of hHBP.

As the HBP homologues are targets of the claimed antibodies, Applicant has not provided a sufficient enabling description of all the antibodies that are capable of binding to all the homologues of HBP for the following reasons.

Other than the antibodies binding to the disclosed species of "hHBP homologous", i.e., hHBP, pHBP and hNEL, there does not appear to be an actual reduction to practice of an antibody that binds other species of homologous of HBP, nor is there a complete or partial structure of an antibody capable of binding a HBP that is other than hHBP, pHBP or hNEL in detailed drawing or through a structural chemical formula, e.g., sequence of the antibody.

Furthermore, a skilled artisan is well aware that such antibodies binding to hHBP, pHBP or hNEL would not be predictive of other antibodies that are able to bind to all members of the genus of homologues of hHBP. For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991; see entire document) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody. Further, Li et al. (PNAS 77: 3211-3214, 1980; see entire document) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims 1, 3, 4, 6, 7, 10-13, 18, 19, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigen-binding fragment of the antibody that binds to hHBP, does not reasonably provide enablement for any fragment of the antibody. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claim limitation, "a fragment of said antibody" encompasses the antigen-binding fragment as well as any non-antigen-binding fragment of the antibody because the definition provided by the specification does not limit the fragment to only the antigen-binding fragment (see specification on page 13, lines 19-20).

The disclosed use for the antibody commensurate with the scope of the claims is for modulating an inflammatory response (see page 6, lines 1-25). The disclosure on using the fragments of the antibody for modulating an inflammatory response is limited to only the antigen-binding portions of the antibody because the antibodies and the antigen-binding fragments thereof would have to recognize and bind to the specific epitopes on hHBP in order to exert its pro- or anti-inflammatory activity (see pages 7-10). The specification does not provide any enabling description, i.e., *how to use*, for the non-antigen-binding fragments of the antibodies.

Therefore, one of skill in the art, would not know how to use all the non-antigen-binding fragments of the antibody to modulate inflammatory responses commensurate in scope with the claims and consistent with the instant disclosure without undue experimentation.

11. Claims 6 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following grounds of enablement rejection pertain to a biological deposit:

It is apparent that the cell clone F19A5B4 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell clone. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, Applicant is **required** to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, 7, 10, 11, 12, 13, 18 19, 22, 26, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Flodgaard et al. (WO 00/66151, reference of record, cited IDS, see entire document) as evidenced by Haurum et al. (U.S. Patent 6,849,259, see entire document)

Flodgaard et al. teach a pharmaceutical composition comprising an antibody that binds to hHBP wherein the antibody has anti-inflammatory activity by decreasing the release of bradykinin (see page 16, lines 15; page 6, lines 5-11; page 37, lines 5-8; page 22, line 6). It is noted that the HBP protein taught by Flodgaard et al. has the

identical amino acid sequence of the hHBP set forth in SEQ ID NO: 1 of the present application (see page 9 of Flodgaard).

Given that Flodgaard et al. teach a polyclonal antibody that binds hHBP, and that polyclonal antibodies are known to bind multiple epitopes, at least one of the antibodies in the composition comprising the polyclonal antibody as taught by the prior art would necessarily bind the epitope within the sequence consisting of amino acid residues 20-44 of hHBP set forth in SEQ ID NO: 1.

It is noted that the prior art does not explicitly teach the intended use provided by the claims (e.g., claims 1, 10-13) for the composition, i.e., “for modulating at least one inflammatory response". However, such intended use does not distinguish the composition in the art. See e.g. MPEP § 2114.

Furthermore, given that the prior art teach how to produce an antibody that binds hHBP by immunizing animals with hHBP (see page 16, lines 15-25), one of ordinary skill in the art would readily appreciate the implicit teaching of a cell that produces the antibody because the immunized animals would necessarily have the B cells that produce the antibody.

For claim 29, the limitation of a “recombinant protein comprising the antibody fragment, said fragment being capable of binding to an epitope” reads on a recombinant antibody. It is noted that “recombinant" is a product-by-process limitation for producing the antibody but such process does not distinguish from the antibody in the art because, as evidenced by Haurum et al., polyclonal antibody could be produced via recombinant technology (see, e.g., Abstract).

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Taken together, the teaching of Flodgaard et al. as evidenced by Haurum et al. anticipates the present claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 3, 4, 7, 10-13, 18, 19, 22, 26, 27, 29 are rejected under 35 U.S.C. 103(a) as being obvious over Pereira et al. (U.S. Patent 5,458,874, cited on IDS) in view of Flodgaard et al. (WO 00/66151, cited IDS, see entire document).

Pereira et al. teach an antibody that binds to the epitope within the sequence consisting of amino acid residues 20-44 of hHBP set forth in SEQ ID NO: 1 (see below sequence alignment). It is noted that hHBP is also known as CAP37 (see page 1, line 31 of the instant specification).

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NQGRHFCGGALIHARFVMTAASCFQ      a.a. 20-44 of SEQ ID NO: 1
|||||||||||||||||||||||||
NQGRHFCGGALIHARFVMTAASCFQ      SEQ ID NO: 8 of Pereira et al.
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Pereira et al. teach a bioactive peptide of hHBP (SEQ ID NO: 8) and polyclonal and monoclonal antibodies that binds the peptide (see column 3, lines 28-33 and column 36, lines 22-67). Furthermore, Pereira et al. teach a hybridoma cell producing the antibody (see column 36, lines 58-62).

Although Pereira et al. do not explicitly teach the characterization of the antibody, i.e., *inhibiting at least one inflammatory response associated with hHBP in the absence or presence of a bacterial product*, given that Pereira taught the same or nearly the same antibody binding to the same epitope, the prior art antibody would necessarily inhibit at least one inflammatory response associated with hHBP in the absence or presence of a bacterial product.

Since the Office does not have a laboratory to test the prior art antibody, it is Applicant's burden to show that the prior art antibody does not inhibit at least one inflammatory response associated with hHBP.

Pereira et al. do not teach a pharmaceutical composition comprising the antibody, *per se*. However, given the explicit teaching of Pereira et al. in that the antibody can be used to screen patients for diagnostic purposes (see column 36, lines 63-68; column 40, lines 56-60), it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to put the antibody in a pharmaceutical composition, as evidenced by Flodgaard et al. (see page 22, first complete paragraph). In particular, Flodgaard et al. teach a pharmaceutical composition comprising antibodies to hHBP for diagnosing whether a patient produces hHBP (see paragraph bridging pages 22-23).

A person of ordinary skill in the art would have been motivated to include the antibody taught by Pereira et al. in a pharmaceutical composition to be used for screening and diagnostic purposes as taught by both Pereira and Flodgaard.

It is noted that although motivation to combine the prior art teaching (i.e. for diagnostic purposes) is different from the intended use provided by the claims, i.e., "for modulating at least one inflammatory response"; such intended use does not distinguish the composition in the art. See e.g. MPEP § 2114.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

16. Cell clone F19A5B4 appears to be free of prior art.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Examiner, Art Unit 1644
November 24, 2008

/Phillip Gambel/
Phillip Gambel
Primary Examiner
Technology Center 1600
Art Unit 1644
November 24, 2008